

Notice of Allowability

Application No.

09/471,669

Examiner

Malgorzata A. Walicka

Applicant(s)

ANDERSON ET AL.

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to papers NO. 17-22.
2. ☒ The allowed claim(s) is/are 48 and 51-69.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: _____.
5. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☒ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☒ CORRECTED DRAWINGS must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No. _____.
 - (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
 - (c) ☒ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892) | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____. |
| 5 <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. <u>21</u> . | 6 <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input type="checkbox"/> Other _____. |

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The Amendment under 37 CFR 1.116 filed on Nov. 25, 2002 as paper No.18 is acknowledged. Amendments to claims 63, 64, 67, 68, and 69 have been entered as requested.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 9, 2002 has been entered.

Communication under 37 C. F. R. §§ 1.821-1.825 and Amendment, paper No. 20, and Information Disclosure Statement under 37 CFR §1.97 and §1.98, paper 21, both filed on Dec. 9, 2002 are acknowledged. The substituted sequence listing has been entered.

The Preliminary amendment filed on Dec. 19, 2002 as paper No. 22 is acknowledged. The amendments to claims 58, 61, and 67 have been entered.

Claims 48, and 51-69 are the subject of this Office Action. Claims 1-47 and 70-113 are withdrawn from consideration as drawn to the nonelected invention.

1. Examiner's amendment

F This application is in condition for allowance except for the presence of claims 1-47 and 70 -113 drawn to inventions non-elected without traverse. Accordingly, claims 1-47 and 70-113 have been cancelled.

2. Allowance

2.1. Claims 48 and 51-69 are allowed. The following is the examiner reason for the allowance.

Applicants disclose nucleic acid molecules encoding human β -secretase enzyme (SEQ ID NO: 2) and its naturally truncated forms (SEQ ID NOs: 43, 57, 58, 59, 60, 66, 67, 68, 69, 70, 74, and 75). The inventions are free of prior art. The closest prior art is the publication EP 0855 444 A2, by Powell et al., issued on July 27, 1998 setting forth the nucleic acid encoding human β -secretase. The DNA molecule taught by Powell et al. has in position 389 adenine, whereas the nucleic acid of the present application has in position 389 thymidine, thus the amino acid in position 130 of the β -secretase disclosed by Powell et al. is glutamic acid, whereas that of the instant application is valine. Therefore, the nucleic acid molecule of Powell et al. is distinct from the claimed nucleic acid molecule and the prior art provides no suggestion to modify the nucleic acid molecule of Powell et al. to produce the sequence claimed in the instant application. As such, the claimed nucleic acid molecules are novel and non-obvious. Human β -secretase is an enzyme involved in producing of β -amyloid peptide highly implicated in Alzheimer disease. The enzyme is, therefore, of high importance in medicine and pharmacology.

2.2. The application having been allowed, the corrected version of formal Fig. 11 filled on Nov. 25, 2002 is required. The description of y-axis of the current version contains multiple typographical errors.

2.3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The date next to J. P. Anderson's name, page 2 of 2, is missing.

In addition, non-initialed and non-dated alterations have been made to the oath or declaration on page 3 of the Supplemental Sheet. See 37 CFR 1.52(c).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (703) 305-7270. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (703) 308-3804. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

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Malgorzata A. Walicka, Ph.D.

Art Unit 1652

Assistant Patent Examiner

Rebecca E. Prouty
REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1600
1605